

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12720



0 - FRONT

12-18-97

INCIDENT REPORT

2 p 3 p

Date of Incident: November 21, 1997

Incident No. [REDACTED]

Case No: [REDACTED]

Received: 9:53 am

Arrived: 9:57 am

Cleared: 10:15 am

Incident: Request for Ambulance

Location: [REDACTED]

Time Reported: As Above

Date/Time Discovered: 11/21/97 9:53 am

() Student () Faculty () Staff (X) Deceased () Witness
() Arrested () Warning () Driver (X) Victim () Other:

Name: [REDACTED] Address: [REDACTED]
Home Address: [REDACTED]

Sex: M Race: W DOB: [REDACTED] SSN: [REDACTED] Phone No: [REDACTED]
Home Phone: [REDACTED]

() Student () Faculty () Staff () Complainant (X) Witness
() Arrested () Warning () Driver () Victim () Other:

Name: [REDACTED] Address: [REDACTED]

Sex: M Race: W DOB: [REDACTED] SSN: [REDACTED] Phone No: [REDACTED]

() Student () Faculty (X) Staff () Complainant () Witness
() Arrested () Warning () Driver () Victim () Other:

Name: [REDACTED] Address: [REDACTED]

Sex: M Race: W DOB: [REDACTED] SSN: [REDACTED] Phone No: [REDACTED]

() Student () Faculty () Staff () Complainant () Witness
() Arrested () Warning () Driver () Victim () Other:

Name: [REDACTED] Address: [REDACTED]

Sex: M Race: W DOB: [REDACTED] SSN: [REDACTED] Phone No: [REDACTED]

NARRATIVE

cc: [REDACTED]

Investigating Officer: [REDACTED]

Date: 11/21/97

Assisting: [REDACTED]

Attachment #:
12-18-97
1 p. of 3 p.

[REDACTED]

INCIDENT REPORT

Date of Incident: November 21, 1997

Incident No: [REDACTED]

Case No: [REDACTED]

On Friday, November 21, 1997 at 9:53 am Protective Services was notified that a [REDACTED] Mr. [REDACTED] had collapsed in the men's locker room [REDACTED]. I was dispatched at 9:54 am. I arrived at 9:57 am. I was directed to the basement men's lockerroom. I entered the lockerroom and saw two men giving Mr. [REDACTED] 2 man CPR. They were Mr. [REDACTED] giving chest compressions and Mr. [REDACTED] was giving mouth to mouth. There was another [REDACTED] calling out [REDACTED] name trying to get a response. [REDACTED] roommate was there. As I was talking to [REDACTED] roommate, the emergency personnel arrived at the scene and took control. I then directed people, not needed, out of the way so EMS people could work.

About 10:07 am the victim was transported to [REDACTED]. I then talked to Mr. [REDACTED] to find out what happened. Mr. [REDACTED] told me that he saw Mr. [REDACTED] at about 5:30 am 11/21/97 working out trying to cut weight for [REDACTED]. He then told me that he saw Mr. [REDACTED] at about 7:30 am with Asst. Coach [REDACTED]. Mr. [REDACTED] told Mr. [REDACTED] that he was a little short of breath. After that Mr. [REDACTED] said that he had to go teach a class.

I then talked with Mr. [REDACTED] and he told me that he was with Mr. [REDACTED] at about 7:30 am. He told me that Mr. [REDACTED] had about 4 lbs to lose to make weight for [REDACTED]. He also told me that at 7:30 am Mr. [REDACTED] had only 1/2 pound to lose.

Mr. [REDACTED] told me that at about 9:45 am Mr. [REDACTED] and himself came out of the showers. He told me that Mr. [REDACTED] had on a rubber suit with a sweat suit over the top of the rubber suit. They exited the showers together. Mr. [REDACTED] had taken the two suits off. Mr. [REDACTED] told me that Mr. [REDACTED] was in and out of consciousness. Mr. [REDACTED] told me he checked for a pulse and there was one. He then said a few moments later Mr. [REDACTED] collapsed. He then checked for a pulse again and there was no pulse. Mr. [REDACTED] told me that a fellow [REDACTED] came in and he sent them to call for help. He then told me that Mr. [REDACTED] and Mr. [REDACTED] came in and started CPR.

At 10:21 am I went to [REDACTED] and at 10:35 am Mr. [REDACTED] was declared dead by Dr. [REDACTED].

Investigating Officer: [REDACTED]

Date: 11/21/97

Assisting: [REDACTED]

Attachment #5
12-18-97
3 p of 3 p.

INCIDENT REPORT

Date of Incident: November 21, 1997

Incident No: [REDACTED]

Case No: [REDACTED]

() Student () Faculty (X) Staff () Complainant () Witness
() Arrested () Warning () Driver () Victim () Other:

Name: [REDACTED]

Address: [REDACTED]

Home Address: [REDACTED]

Sex: M Race: W DOB: [REDACTED]

SSN: [REDACTED]

Phone No: [REDACTED]

Home Phone: [REDACTED]

NARRATIVE

Just prior to 10:00 am I received a call from [REDACTED] and was told there was a [REDACTED] having trouble in locker room # 18. I checked with the switchboard operator and was told that 911 had called and said that [REDACTED] was on the way to [REDACTED] and that Officer [REDACTED] had been dispatched to the scene. A few minutes later I was called by Officer [REDACTED] and he requested that I come to the scene right away, which I did.

Upon arrival [REDACTED] personnel was doing CPR on a White/Male in locker room [REDACTED] Officer [REDACTED] and I were requested to get non essential personal out of the locker room which we did. Shortly the [REDACTED] Fire Department arrived to assist.

After the victim, Mr. [REDACTED], was removed, I talked to Mr. [REDACTED] and was told that Mr. [REDACTED] had been working out since 5:30 this morning to [REDACTED] for [REDACTED]. Just prior to Mr. [REDACTED] collapsing he had been riding a stationary bike in the shower room of locker room [REDACTED]. We proceeded to this area and upon entering noted that the room was quite warm and located in the showers were 4 stationary bikes. Lying on the floor, in a heap, was a sweatsuit and a rubberized body suit. Mr. [REDACTED] said that he had been with Mr. [REDACTED] since 8:00 am and that Mr. [REDACTED] was working out very strenuously to [REDACTED] for a [REDACTED].

I noted that several [REDACTED] were in the area and appeared to be having a tough time dealing with this incident so I contacted [REDACTED] and asked that grief counselors be sent to the scene. I also notified [REDACTED] and [REDACTED] about the incident.

The sweatsuit and rubber suit were brought to the Information Center, hung in the evidence room to dry out. Both were quite wet from perspiration.

I then talked to Mr. [REDACTED] and he stated that he had been in his office when a [REDACTED] came in and said that he was needed right away in locker room [REDACTED]. There was a real sense of urgency in the [REDACTED] face and he went right away. At the scene was Mr. [REDACTED] and they started CPR when they could not detect a pulse. He did not think more that a minute had passed from the collapse to when CPR was started.

Investigating Officer: [REDACTED]

Date: 11/21/97

Assisting: [REDACTED]

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I arrived at the [REDACTED] at about 7:40 a.m. on Friday. Weigh-ins began at about 8:00 a.m. I talked with [REDACTED] a couple minutes after weigh-ins and we talked about working out in the [REDACTED] showers in order to lose 1.75 lbs. Around 8:15 I carried a bike down to the showers where five [REDACTED] were starting to work out on other bikes. I worked mostly with [REDACTED] for thirty to forty minutes on the bikes doing alternating riding. [REDACTED] and I walked down to check his weight about 8:45 or 8:50. [REDACTED] was one half pound over 153. I weighed one other [REDACTED] in and sat and talked with another for awhile. I walked over to [REDACTED] locker and talked with him about what he wanted to do. He had drank some water and was sitting by his locker without any thing on. We relaxed for awhile and some guys were around and we were encouraging him. About 9:10 a.m. I went down and got some dry clothes for [REDACTED]. We walked down to start working out between 9:15 and 9:20 a.m. [REDACTED] and I only wanted to go about 15 minutes on the bike or until he broke a sweat. We started to work on one bike somewhere around 9:20 and 9:25. [REDACTED] biked for about 5-10 minutes and we went to another bike. [REDACTED] tried riding the bike but his feet kept slipping off the pedals—the bike was broken. I checked his back and he was sweating. [REDACTED] got off the bike and I moved the bike so we wouldn't get wet. I looked at [REDACTED] and he looked like he might pass out. This must've been somewhere between 9:35 and 9:45. I helped him out of the shower and began peeling his clothes off. I then took him out to the locker room and got him some water. He took about three swallows and another [REDACTED] came in to the room. I started to run and get [REDACTED] but then turned around to have the [REDACTED] go get him. I sat with [REDACTED] in my lap and poured cold water on his head and chest. He did have a pulse but was not responding to me. [REDACTED] and others came in and then left and [REDACTED] stopped breathing. I started CPR and [REDACTED] came in and took over. I don't know how long this went on but the EMT arrived soon after.

Statement of [REDACTED]
November 24, 1997

[REDACTED]
Protective Services [REDACTED]

000004

SEC-18-1997 16-17

Thursday night practice was a very intense practice that went from 4:00 - 5:20 p.m. . I talked with [REDACTED] on his way out of [REDACTED] to go home around 6:15 p.m. and his spirits were good he was 3.5 pounds over 153 pounds which was the weight he wanted to make the next morning.

Friday morning [REDACTED] began working out at 5:30 am . He was running, biking and would sit and rest approximately every 20 minutes to let his sweat continue. At 5:50 a.m. I asked him how much he had to lose and he replied 4 pounds. I could see the sweat running off his forehead and thought he had a good sweat going. [REDACTED] continued this workout until 6:40 am .

6:45 a.m. I met [REDACTED] downstairs in the hallway on his way to the locker room to check his weight. In passing in the hallway he asked me "Do you ever get a shortness of breath when you're cutting weight?" I replied, "You will feel better once you weigh in". At that point I continued on my way upstairs and [REDACTED] went into the locker room to check his weight. Having a shortness of breath can be common and his appearance looked good so I did not think anything about his statement. [REDACTED] relaxed in the locker room until 7:10 a.m.

6:50 a.m. I called [REDACTED] on the phone at his apartment to make sure he was awake and would be to [REDACTED] by 7:45 am to get ready for weigh-ins.

7:10 a.m. [REDACTED] came back into the [REDACTED] room and began biking until 7:40 a.m. . At this point everyone in the [REDACTED] room went down to the locker room for weigh-ins. There was a class coming in the [REDACTED] room at 7:45 a.m. so everyone left the room and went to the locker room. Weigh-ins began at 8:00 a.m. .

8:05 a.m. [REDACTED] weighed in and was 1.75 pounds over 153 pounds. At 8:10 a.m. [REDACTED] asked [REDACTED] "Where should I go to workout?" [REDACTED] replied that the shower area would be a good place.

8:20 am [REDACTED] and [REDACTED] went into the shower area to bike. There were four other [REDACTED] in the shower area at that time. [REDACTED] biked until 8:40 am.

8:50 a.m. [REDACTED] weighed in and was .5 pounds over. He sat down and had approximately 8 ounces of water and relaxed until 9:20.

9:20 a.m. [REDACTED] went into the shower area with [REDACTED] and biked until 9:30. At 9:30 he got off the bike to go and weigh in. When he stood up he said he did not feel very good. [REDACTED] helped him take off his sweats and sat him down in the locker room area. [REDACTED] became very lethargic and [REDACTED] sent a [REDACTED] to

000005

[REDACTED]

get help.

9:40 a.m. I came into the locker room and found [REDACTED] sitting on the ground leaning against [REDACTED]. He was unresponsive. I sent a [REDACTED] to call for an ambulance and another one to get [REDACTED] the head trainer. I ran upstairs to get more help and returned about 1 minute later.

9:45 am [REDACTED] and [REDACTED] began CPR.

Statement of [REDACTED]
November 24, 1997

[REDACTED]
Protective Services [REDACTED]

000006

[REDACTED]

November 21, 1997

9:45 - 9:50 [REDACTED] hurried into my office between 9:45 & 9:50 saying we need you down stairs now. I could tell by the look in his face it was something serious though he did not say anything more. He led me to the locker room where [REDACTED] was on the floor. [REDACTED] had a t-shirt and sweat pants on. His skin was very wet. [REDACTED] pupils were fixed and dilated.

[REDACTED] said [REDACTED] did not have a pulse. He asked me what he should do. I gave [REDACTED] my keys and told him to call an ambulance. I checked [REDACTED] carotid pulse and found none. I told [REDACTED] to provide ventilation while I performed compressions.

Throughout CPR I told [REDACTED] he was doing fine. At one point I told him to not be so forceful with his breathing. CPR was mechanically correct - I compressed the sternum [REDACTED] breathes entered and exited [REDACTED] lungs. Throughout CPR I checked [REDACTED] pulse - 3 - 4 times. As we progressed [REDACTED] chest became more rigid and the abdomen distended.

At one point I looked up to see [REDACTED] sitting next to [REDACTED] [REDACTED] I also remember looking up and seeing the clock at 9:53.

10:10 - 10:20 The paramedics arrived and took over. They put electrodes on [REDACTED] chest but did not shock him. Their equipment advised against shocking.

I rode in the ambulance to [REDACTED]

[REDACTED]

[REDACTED]

12/1/1997

[REDACTED]

000007

Love Love

Memorandum

DATE: 12/31/97

FROM: Jeffry A. Bernhardt, Investigator
[REDACTED] Resident Post

SUBJECT: Medical Records for [REDACTED]

TO: Cheryl Bigham, SI

As requested I obtained the medical records for [REDACTED] On 12/23/97 I visited [REDACTED] the mother, and obtained her signature on 5 medical release forms and also the location of the physicians that [REDACTED] had seen throughout his life. A total of two physicians were indicated, Dr. [REDACTED] and Dr. [REDACTED] On 12/30/97 both doctor's offices were visited. I provided an original medical release form, an FDA-482 Notice of Inspection noted for record collection only, and my credentials to the medical records person at each office [REDACTED] Receptionist at [REDACTED] and [REDACTED] Medical Records Clerk at [REDACTED] and obtained copies of the medical records.

TO: Dave Yost, ADIB

Attached are the medical records and spare medical release records obtained on [REDACTED] per ADIB Manresa's request.

Dan M. Manresa
for Cheryl A. Bigham, SI

Attachments: (4)

ORIG: DRYost, ADIB
cc: MIN-DO / EF
[REDACTED] RP / EF

98 JAN 12 P2:37

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

000008

Memorandum

According to Mrs. [REDACTED] Dr. [REDACTED] was [REDACTED] doctor from birth to age 18 and Dr. [REDACTED] from that age to the time of his death. Mrs. [REDACTED] also stated that only other physicians that would treated [REDACTED] would have been associated with the [REDACTED] which she did not have knowledge of. Mrs. [REDACTED] was aware that [REDACTED] had received a prescription for Valtrex (Valacyclovir HCl) to treat a rash and mentioned a Dr. [REDACTED] who had recommended it. Investigator Keer mentioned Dr. [REDACTED] name during a phone conversation with him on 12/23/97 and I believe he has spoken with Dr. [REDACTED] and that Dr. [REDACTED] is affiliated with the [REDACTED]

Copies of the medical records are attached as well as the additional medical release forms.



Jeffrey A Bernhardt
Investigator
MIN-DO, [REDACTED]

Attachments/Exhibits:

- 1) 482, 463a, and records from Dr. [REDACTED]
- 2) 482, 463a, and records from Dr. [REDACTED]
- 3) Business cards for the above Doctors.
- 4) Additional medical release forms.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
U. S. FOOD AND DRUG ADMINISTRATION
[REDACTED] DISTRICT OFFICE

Love
12720
MEMORANDUM

DATE: January 27, 1998

TO: Edith Snyder, S.I.

FROM: William E. Keer, RIC [REDACTED]

SUBJECT: [REDACTED] Death

On 12-17-97 I received a telephone call from Edith Snyder, S.I. During this call I was requested to initiate a death investigation for a Mr. [REDACTED] and [REDACTED]. The investigation was to focus around the [REDACTED] possible use of the nutritional supplement creatine. Upon completion of the telecom, I call the [REDACTED] and the Medical Examiner [REDACTED]. Because it was late in the day, no contacts were made.

On 12-18-97, I spoke with [REDACTED] Director to the [REDACTED] Mr. [REDACTED] stated that the health department was not working on the case and they were not aware of any relationship between the death of this [REDACTED] and the use of nutritional supplements. I then spoke with Mr. [REDACTED] Medical Examiner. Mr. [REDACTED] indicated that the [REDACTED] died of hyperthermia. He said that at the time of his death, Mr. [REDACTED] had a temperature of 108 degrees Fahrenheit. I made arrangements to pick up the final gross and microscopic anatomical autopsy later in the day.

I then went to [REDACTED] to interview Mr. [REDACTED] coach. He was not available. However, I spoke with a former [REDACTED] coach, [REDACTED]. He did not provide me with much information. As I worked my way down the hallway, I ended up speaking with Mr. [REDACTED] Athletic Trainer. Mr. [REDACTED] stated that he would make arrangements for me to speak with Mr. [REDACTED] and Mr. [REDACTED], the deceased's best friend and fellow [REDACTED] at 10:30am. Since I had an hour before the next meeting, I decided to visit Mr. [REDACTED] apartment at [REDACTED]. Upon arriving at the apartment I ran into Mr. [REDACTED] former roommate. Mr. [REDACTED] provided me with the following information.

[REDACTED] and [REDACTED] have been friends and follow [REDACTED] for two years. They began rooming together at the beginning of this school year. [REDACTED] majored in English and [REDACTED] majored in Elementary Education. [REDACTED] started the school year weighing approximately 178 lbs. He wanted to [REDACTED] in the 153 lb. weight class. He started dieting in approximately the middle of September 1997. [REDACTED] showed me cans of nutritional supplements [REDACTED] may have consumed prior to his dieting regimen. They were:

Endorsement:

7/1/98
TO: Thomas P. Nelson, Acting
Director, Investigations Branch, MIN-DO (HFRLES50)

(This memorandum was misplaced and not found until last week.)
It describes the investigation of a 22-year old's death. Samples
98-571-612, creatine, and 98-571-613, Rippat Fack, were collected from the deceased
apartment.
No further follow-up planned by MIN-DO.

O: MIN-DO
cc: Brenda Alois, HFS-636 4/16/98

M. Edith Snyder
Supervisory Investigator
000010

U.B.N. "Just Be Natural"
Creatine
Coded 5022 12

and

Twinlab
Ripped Fuel
Coded 71047

Prior to leaving Mr. [REDACTED] residence I collected these items. C/R #98-571-612 contains the creatine and C/R # 98-571-613 is the Ripped Fuel. He surmised that these items were purchased locally. [REDACTED] stated that he is positive that [REDACTED] did not consume any of these items after September. He stated that these products cause fluid retentions and that would defeat the dieting attempts. [REDACTED] stated that [REDACTED] was a clean cut All-American boy. He did not smoke. He did not have any alcohol problems. He did not use illegal drugs. He did not overeat. He had not consumed any beer since September. He did not participate in any activities that would obviously threaten his health. He was well liked. He had no enemies. He did not have a serious girlfriend. [REDACTED] added that [REDACTED] generally consumed a gallon of water daily. He stated that two days before his death, [REDACTED] stopped drinking water to facilitate his weight loss. [REDACTED] was not sure if [REDACTED] ate any solid foods during this period. He may have been taking Valtrex for a herpes type of infection. The Valtrex was prescribed by Dr. [REDACTED] local physician. On 12-19-97, Mr. [REDACTED] signed an affidavit (Attachment #1) pertaining to the dietary supplements collected and his statements about Mr. [REDACTED]

At 10:30 a.m., I returned to [REDACTED] and interviewed [REDACTED] and [REDACTED]. All of these individuals confirmed Mr. [REDACTED] statements. They did not add any new or useful information.

At 2:00 p.m., I visited the local Medical Examiner, Mr. [REDACTED]. Mr. [REDACTED] could not understand why the FDA and the press were so interested in the case. He stated that it was obvious the [REDACTED] died of hyperthermia. He stated that the individual was trying to lose weight by wearing a rubber suit under a sweat suit while riding a stationary bicycle in a steamy shower room. After being transported to the hospital and being pronounced dead, he had a temperature of 108 degrees Fahrenheit. He stated that one hour after death his temperature was still 107 degrees Fahrenheit. During this visit Mr. [REDACTED] provided me with the attached copies of:

Attachment #2	Medical Examiner Case File . . . Case # [REDACTED] . . . one page
Attachment #3.	Death Investigation Report . . . one page
Attachment #4.	[REDACTED] Autopsy Report . . . three pages.
Attachment #5	[REDACTED] Protective Services (campus police) Incident Reports . . . three pages
Attachment #6	[REDACTED] Police Department Report . . . three pages
Attachment #7	[REDACTED] Athletic Training Pre Season Physical Screening . . . three pages

He stated that the toxicology screens are not completed. However, he expected the results soon.

I ask him to fax me a copy when they were available and left.

In response to a request from S.I. Snyder, I called Mr. [REDACTED] on 12-19-97. I asked him if enough blood was available to run test for creatine and mahuang (ephedra). He stated that there was and agreed to have the blood sent to [REDACTED] for additional tox. screens.

Several times between 12-19-97 and 12-23-97, I called the [REDACTED] County Medical Examiner's office in hopes that the chemical testing reports were in. The last time, I spoke with Ms. [REDACTED] Asst. M.E. She stated that the tox. screens take "forever" and that Mr. [REDACTED] would contact me when they arrive. She also told me that Dr. Lori Love (FDA) called her office requesting these results.

As of 3:30pm on 12-23-97, the tox screens have not arrived.

The following paragraphs are attempts to answers the questions asked by DEIO for this investigation. All of the answers were derived from previously mentioned interviews, documents and an additional 12-22-97 interview with [REDACTED]

Medical History:

According to the people interviewed and the preseason physical screening document, Mr. [REDACTED] did not have any cardiac or renal disease. Mr. [REDACTED] stated that his friend was not bulimic. [REDACTED] was not subject to passing out.

[REDACTED] weight at the beginning of the year was 178 lbs. The night before his death his weight was 156.5 lbs. According to the preseason screen document his weight varied between 150 lbs. and 180 lbs. His last method of dieting appears to have included fasting and not drinking any liquids. He stopped drinking water two days prior to his death. [REDACTED] was not into purging, using laxative, or weight loss drugs.

Although he processed containers of Creatine and Ripped Fuel, his friends stated that he would not have used them because of his diet. Apparently, [REDACTED] believe these items cause water retention.

The family's medical history is unknown.

[REDACTED] did not have any alcohol since the middle of September. He did not smoke. However, according to friends, he occasionally dipped snuff tobacco (two or three times this school year).

Autopsy:

All information pertaining to the autopsy is attached. Rectal temperature was listed as 41.8 degrees Centigrade approximately one hour after death. Tox. screens are being run and they are not available as on this writing.

Activities on the day(s) before death:

At the time of his death, he was wearing a rubber suit under a sweat suit while riding a stationary bicycle in a shower room with the hot water running. The temperature of the room is unknown. It was considered steamy. Friends stated that they did not think [REDACTED] had anything to drink for two days. They also thought he had been fasting for two days. He had no illness symptoms the day of his death. He may have been taking Valtrex for a herpes infection.

[REDACTED] history:

According to his friends, [REDACTED] and during his [REDACTED] at [REDACTED]. During his [REDACTED] and [REDACTED] years he went to [REDACTED] at [REDACTED] was not offered at the [REDACTED] extension. His weight class for the last two years had been 153 lbs. Generally [REDACTED] practice was between 4:00 p.m. and 6:00 p.m. daily. However, the gym and the weight equipment were always available for use by the athletes at any time. [REDACTED] died one day before his next match.

Attachments:

Attachment #1	Affidavit signed by Mr. [REDACTED] the deceased's roommate
Attachment #2	Medical Examiner Case File . . . Case # [REDACTED] one page.
Attachment #3	Death Investigation Report . . . one page.
Attachment #4	[REDACTED] Autopsy Report . . . three pages.
Attachment #5	[REDACTED] Protective Services [REDACTED] police) Incident Reports . . . three pages
Attachment #6	[REDACTED] Police Department Report . . . three pages
Attachment #7	[REDACTED] Athletic Training preseason Physical Screening . . . three pages.

William E. Keer
William E. Keer
Investigator [REDACTED]
[REDACTED]